UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

THOMAS E. SPRINGER, in his capacity as Trustee of the Chapter 7 Bankruptcy Estate of Rocio Herrera-Nevarez, Plaintiff, v. ETHICON, INC. and JOHNSON & JOHNSON, Defendants.	Case No. 1:17-cv-03930 Honorable Matthew F. Kennelly

DEFENDANTS ETHICON, INC. AND JOHNSON & JOHNSON'S MEMORANDUM IN SUPPORT OF THEIR OMNIBUS MOTION *IN LIMINE* [1]

[1] For ease of reference, Defendants have preserved the original numbering from the motions *in limine* that were filed while this case was pending in the Southern District of West Virginia. However, pursuant to the Court's Minute Entry dated July 14, 2017, the motions presented herein are self-contained and do not require reference to prior briefs.

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Motion in Limine No. 3: The Court should preclude Plaintiff from introducing evidence of post-implant revisions to the IFU and patient brochure.

The TVT-O IFU and patient brochure have been revised on several occasions, most recently in 2015. Any revisions made after Ms. Herrera-Nevarez's May 13, 2005 implant surgery should be excluded pursuant to Rules 407 and 403.

Ethicon anticipates that Plaintiff will seek to admit evidence regarding the 2015 revisions to the TVT-O IFU.[2] *See* Pl. Resp. (Dkt. 135), at 4-6. These revisions were made after an exchange with Health Canada, the Canadian regulatory authority. Some of the changes were requested by Health Canada, while others were volunteered by Ethicon. *See* Ex. A, Ethicon Letter to FDA re: Add-to-File Submission for TVT-O, Apr. 8, 2015. After Ethicon decided on the Canadian changes, it contacted the FDA about making the same changes in the United States. *See* Ex. B, Weisberg 11/13/15 Dep. Tr. 491:20-492:23, *In re: Pelvic Mesh/Gynecare Litig.*, No. 291 CT (N.J. Super. Ct. Law Div.).

The FDA did not ask Ethicon to implement the Health Canada changes in the United States; rather, they were purely voluntary. *Id.* at 492:25-494:2.[3] Ethicon made the changes for the purpose of uniformity. The IFU changes were not medically or legally necessary because they relate to complications that were already commonly known to pelvic floor surgeons Ex. C, Weisberg 11/12/15 Dep. Tr. 90:11-91:3, *In re: Pelvic Mesh/Gynecare Litig.*, No. 291 CT (N.J. Super. Ct. Law Div.); *see Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 42 (Ill. 2002) ("A corollary of that doctrine is the principle that a prescription medical device manufacturer need not provide a warning of risks already known to the medical community.").

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[2] Defendants Ethicon, Inc. and Johnson & Johnson are collectively referred to as "Ethicon."

[3] The FDA only asked to see redline versions of the changes and recommended some minor revisions. *Id.* at 497:8-498:9, 500:21-503:18; *see also* Ex. D, Add-to-File for TVT-O (showing redline of changes to U.S. IFU); Ex. E, Emails from Sharon Andrews to Stacy Kluesner, June 4, 5, 2015.

Under Rule 407, the 2015 revisions, along with other post-implant labeling changes, constitute inadmissible subsequent remedial measures. The Seventh Circuit has expressly held that Rule 407 bars the admission of subsequent labeling changes for medical devices. *See Chlopek v. Fed. Ins. Co.*, 499 F.3d 692, 696-700 (7th Cir. 2007) (holding that Rule 407 bars the admission of subsequent label changes for Class II medical device); *see also Sosnowski v. Wright Med. Tech., Inc.*, No. 11 C 59, 2012 WL 1030485, at *5 (N.D. Ill. Mar. 27, 2012) ("[E]vidence that defendant now recommends that patients over 230 pounds use a hip prosthesis with a cobalt chromium neck, is not admissible to show that the titanium design was defective."); *In re Depakote*, 87 F. Supp. 3d 916, 925 (S.D. Ill. 2015) (finding that Rule 407 bars admission of label changes to a prescription drug).[4]

Plaintiff may attempt to argue that the 2015 revisions should be admissible because they were made at the behest of a Canadian regulatory authority. However, this argument fails for at least two reasons. First, as noted above, all changes made to the IFU in the United States were purely voluntary. Second, the Seventh Circuit has emphasized that the *reason* for the label change is irrelevant for purposes of Rule 407. In *Chlopek*, the plaintiffs attempted to "sidestep Federal Rule of Evidence 407" by arguing that the label change "was not prompted by safety concerns." *Chlopek*, 499 F.3d at 700. The Seventh Circuit rejected this argument, emphasizing that the *reason* for the label change is irrelevant:

[4] *Accord DeLuryea v. Winthrop Labs., a Div. of Sterling Drug, Inc.*, 697 F.2d 222, 227-29 (8th Cir. 1983) (holding all exhibits, documents, articles, package inserts and Physicians' Desk Reference warnings after drug was taken were inadmissible); *Lindsay v. Ortho Pharm. Corp.*, 637 F.2d 87, 94 (2d Cir. 1980) (granting new trial where trial court admitted subsequent label revisions for purpose of proving inadequacy of prior warnings); *Werner v. Upjohn Co.*, 628 F.2d 848, 853 (holding admission of subsequent label revisions for purposes of proving negligence was "impermissible and constitute[d] reversible error"); *Hill v. Novartis Pharm. Corp.*, 944 F. Supp. 2d 943, 960 (E.D. Cal. 2013) ("Evidence that a manufacturer changed a product's warning label after a plaintiff was allegedly injured by the product is not admissible in a failure-to-warn case.") (relying on *Chlopek*).

> But Breg's *motive* for making the change is irrelevant. All the rule requires is that the measure "would have made the injury or harm less likely to occur." Fed.R.Evid. 407. Regardless of Breg's stated reason for the change, the plaintiffs undoubtedly wanted the jury to conclude that Breg added the warning because the product was unsafe without it. That is precisely the type of inference that Rule 407 forecloses, in order to avoid discouraging the taking of remedial measures.

Id. (emphasis in original). Here too, Ethicon's purported *reasons* for making revisions to the IFU, such as an exchange with Canadian officials, are irrelevant for purposes of Rule 407.

Further, evidence regarding subsequent labeling changes should be excluded pursuant to Rule 403 because the probative value of such evidence is substantially outweighed by the danger of confusing the issues and wasting valuable trial time. If Plaintiff introduces evidence regarding the 2015 revisions, then Ethicon will need to explain the circumstances under which those revisions were made. This will not only require evidence regarding the Canadian regulatory process, but will also open the door to previously excluded evidence regarding the FDA 510(k) clearance process.

First, Ethicon will need to explain what prompted the changes in Canada. At a minimum, Ethicon will have to inform the jury of the relevant regulatory history of TVT-O in Canada, the differences between the Canadian and U.S. regulations governing IFUs, and the differences between the decision-making processes used by Canadian and U.S. regulatory authorities to implement labeling changes. "Absent such background and context, a jury might be more inclined to abdicate its responsibilities and defer to the negative decisions of [the] foreign regulators regarding [the product's] safety." *In re Seroquel Prods. Liab. Litig.*, 601 F. Supp. 2d 1313, 1318 (M.D. Fla. 2009). In a nine-day trial, this type of detour would be prejudicial to Ethicon, confusing to the jury, irrelevant to the issues in this case, and a waste of time. FED. R. EVID. 401, 402, and 403.

Second, evidence about the 2015 revisions would open the door to evidence about the 510(k) clearance process. The MDL court has ruled that evidence regarding the 510(k) process is inadmissible, Order (Dkt. 148), at 2-3. However, if the jury hears evidence about the 2015 revisions, then Ethicon will need to inform the jury that those revisions were not required by the FDA. This, in turn, will require introducing certain evidence regarding the FDA regulatory process for 510(k) devices. The FDA classified TVT-O as a Class II device based on its decision that TVT-O does not present a "potential unreasonable risk of illness or injury." 21 U.S.C. § 360c (describing Class III device). It did that in two proceedings: the initial 510(k) clearance in 2003, and then a second clearance in 2012 after it conducted a special hearing into the safety of pelvic mesh devices. The FDA then endorsed the safety and effectiveness of the devices like TVT-O in 2013. In none of these reviews — not 2003, not 2012, and not 2013 — did the FDA ever mandate a label change or suggest that the TVT-O IFU was in any way inadequate. Rather, the changes were made only when Ethicon went to the FDA in 2015 and suggested them. Even then, the FDA expressly did not require a new 510(k) clearance process for the changes. Ex. E, Email from S. Andrews (June 5, 2015).

If Plaintiff attempts to introduce evidence regarding the revisions to the IFU, then Ethicon should be permitted to offer this explanatory history to show that the revisions were purely voluntary and not mandated by the FDA. *See U.S. v. Lerch*, 996 F.2d 158, 162 (7th Cir. 1993) ("the 'curative admissibility' doctrine allows introduction of inadmissible or irrelevant evidence where other party opens the door") (quoting *U.S. v. Whitworth*, 856 F.2d 1268, 1285 (9th Cir. 1988)).

Finally, Ethicon notes that this case is distinguishable from *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, No. 14 C 1748, 2017 WL 2313201, at *1-2 (N.D. Ill.

May 29, 2017) (Kennelly, J.). First, as noted above, the label changes made in 2015 were voluntary, not mandated by the FDA.[5] Second, Dr. Vassallo testified that he did not rely on the IFU in treating Ms. Herrera-Nevarez and has not reviewed the IFU "for many years." *See* Ex. F, Vassallo 12/16/15 Dep. Tr. 43:20-24, 157:7-18 ("Q: Did you rely on this IFU package insert in your recommendation of TVT-O to Ms. Herrera in 2005? A. No.; Q. Did you rely on this IFU package insert for information about risks related to the May 2005 procedure? A. No."). Thus, subsequent revisions to the IFU are not relevant to Dr. Vassallo's decision to use the TVT-O. Third, Ethicon does not intend to contest general causation with respect to the adverse reactions added in the 2015 revisions. *Cf. In re Testosterone Replacement Therapy Prods. Liab. Litig.*, 2017 WL 2313201, at *1-2. Accordingly, any subsequent label changes should be excluded.

Motion in Limine No. 4: The Court should exclude in-court demonstrations or testing of exemplar devices.

As a threshold matter, Plaintiff should be precluded from introducing into evidence any mesh exemplar devices. Plaintiff does not appear to have identified any mesh exemplars as exhibits or demonstrative aids on the exhibit lists filed with this Court. *See* Second Am. PTO (Dkt. 210), at Ex. B.

To the extent that mesh exemplars are used as demonstrative aids, in-court handling of the mesh exemplars should be prohibited. Any purported probative value of in-court handling of the mesh would be offset by undue prejudice, unfair surprise, or possible confusion of the issues. *See* FED. R. EVID. 403. In particular, in-court demonstrations, testing or even routine handling of the TVT-O that impact the integrity of the device or its mesh component should not be allowed. This is because Plaintiff's counsel and lay witnesses are not equipped or trained to

[5] The voluntary nature of the changes also distinguishes this case from *Gross v. Gynecare*, where a New Jersey court held that revised Prolift warnings were admissible where deemed "mandated" by the FDA. *Gross v. Gynecare*, 2016 WL 1192556, at *21 (N.J. Super. Ct. App. Div. Mar. 29, 2016).

handle the device in the manner in which it is actually intended to be handled by surgeons when implanted or as it actually functions within the body.

The jury should also be prohibited from taking the mesh exemplars into the jury room. "The general rule is that materials not admitted into evidence simply should not be sent to the jury for use in its deliberations." *Baugh ex rel. Baugh v. Cuprum S.A. de C.V.*, 730 F.3d 701, 705 (7th Cir. 2013). "Without the consent of all parties, a deliberating jury may not consider exhibits not actually admitted into evidence." *Id.* at 706; *see also* Ex. G, Trial Tr. at 4722:1-4725:4, *Perry v. Luu, et al*., Case No. S-1500-CV 279 123 LHB (Cal. Super. Ct. Mar. 2, 2015) (holding that the jury could not take the device into the jury room). [6]

Accordingly, Ethicon respectfully requests that the Court issue an order consistent with the protective measures in *Huskey* and *Perry* prohibiting both Plaintiff's counsel and witnesses from touching or handling the TVT-O or similar mesh devices for any other purpose than to show the jury and the Court what the device looks like. In addition, the jury should be prohibited from taking the device into the jury room or otherwise handling it.

Motion in Limine No. 6: Plaintiff should not be permitted to present evidence of other lawsuits against Ethicon, including those concerning Ethicon's other products.

Ethicon anticipates that Plaintiff may attempt to introduce or otherwise rely upon evidence regarding other litigation and claims involving Ethicon, Inc. and Johnson & Johnson, including other mesh products manufactured by Ethicon. This evidence is irrelevant to the issues here, is unreliable hearsay, has no probative value, and runs the risk of improperly impugning Ethicon's character. If admitted, fairness would compel that Ethicon be allowed to rebut it, and

[6] *See also* Ex. H, Trial Transcript at 220:13-18, *Huskey v. Ethicon, et al.*, Civ. A. No. 2:12-cv-05201 (S.D.W. Va. Sept. 4, 2014) ("You only are permitted to visually inspect the product. You are not to conduct a physical exam of the product. Thus, no pulling, tugging, probing or other physical manipulation will be permitted. You are provided the exemplar strictly so you can see what has been described to you in the testimony.").

that would waste trial time on collateral matters. The MDL court has previously granted this motion *in limine*,[7] as have other courts in the mesh litigation.[8] The same ruling applies here.

Motion in Limine No. 9: The Court should exclude evidence or argument relating to medical device reports, reports of adverse events furnished by physicians, summaries of those reports, and/or aggregate numbers of MDRs for TVT-O or any other product.

Ethicon anticipates that Plaintiff will attempt to introduce at trial various Medical Device Reports ("MDRs"). Evidence concerning MDRs and adverse event reports is inadmissible at trial for several reasons.

First, MDRs by "device user" facilities, *i.e.*, hospitals, and physicians who are not required to report, are not admissible by virtue of a federal statute. Congress has declared that these reports are not to be "admissible into evidence or otherwise used in any civil action . . . ." 21 U.S.C. § 360i(b)(3). To admit these MDRs would directly thwart that statutory purpose, as the MDL court noted. *Lewis*, 2014 WL 505234, at *5.

Second, as the MDL court has recognized in the *Daubert* context, MDRs are not a reliable source of information. *Mathison v. Boston Scientific Corp.*, No. 2:13-cv-05851, 2015 WL 2124991, at *18 (S.D.W. Va. May 6, 2015) (quoting from the FDA MAUDE website and holding that "[t]he MAUDE system is a 'passive surveillance system' that does not account for the 'potential submission of incomplete, inaccurate, untimely, unverified, or biased data'"); *see also Carlson v. Boston Scientific Corp.*, No. 2:13-cv-05475, 2015 WL 1931311, at *27 (S.D.W. Va. Apr. 28, 2015); *Mathison*, 2015 WL 2124991, at *18 ("application of the [MAUDE] data to

[7] *See Lewis v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 WL 505234, at *6 (S.D.W. Va. Feb. 5, 2014) (other lawsuits inadmissible under Rule 403); *see also* Ex. I, Order (Dkt. 93), pp. 5-6, *Ramsey v. Boston Scientific Corp.*, No. 2:13-cv-15223 (S.D.W. Va. May 19, 2016).

[8] *See, e.g.*, Ex. J, Order (granting MIL to exclude other lawsuits and investigations), *Carlino v. Ethicon, Inc.*, June Term 2013, No. 3470 (Phila. Cnty. Ct. Com. Pl. Jan. 19, 2016); Ex. K, Order, *Hammons v. Ethicon, Inc.*, May Term 2013, No. 3913 (Phila. Cnty. Ct. Com. Pl. Nov. 30, 2015) (same); Ex. L, Deeming Order, *Beltz v. Ethicon, Inc.*, June Term 2013, No. 3835 (Phila. Cnty. Ct. Com. Pl. Oct. 28, 2016).

reach a scientific conclusion about a manufacturer's conduct is not generally accepted in the scientific or medical community").

Third, MDRs are inadmissible hearsay. Ethicon can only report what it is told by physicians and hospitals in original reports, which themselves are inadmissible under federal law. Even if the reports were business records, that does not cure the hearsay status of the physician and hospital statements on which Ethicon relied in submitting the reports. FED. R. EVID. 805; *Appleby v. Glaxo Wellcome, Inc.*, No. CIV. 04-0062 RBK, 2005 WL 3440440, at *3 (D.N.J. Dec. 13, 2005) (holding "compilations of information or recommendations submitted by outsiders to the FDA, including adverse event reports" are inadmissible hearsay); *Saari v. Merck & Co.*, 961 F. Supp. 387, 397-98 (N.D.N.Y. 1997) (excluding as inadmissible hearsay physician's adverse event statement to the FDA). The MDRs should therefore be excluded.

Motion in Limine No. 11: The Court should exclude Brian Luscombe's internal marketing presentation, the "Top Ten Reason [sic] to Pursue . . . GYNECARE TVT Obturator System."

Ethicon anticipates that Plaintiff will attempt to introduce a farcical PowerPoint presentation by Ethicon employee Brian Luscombe entitled "Top Ten Reason [sic] to Pursue . . . GYNECARE TVT Obturator System." Ex. M. The MDL court excluded this evidence in *Huskey* and *Edwards*, ruling that the risk of unfair prejudice from the introduction of the "Top Ten" presentation substantially outweighs any probative value of that presentation. The MDL court held that the presentation "is a poor attempt at humor," and "is not probative to any claims in this case. Even if it were probative, I would exclude it under Rule 403 for its risk of unfair prejudice and its potential to waste time in trial." *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3861778, at *3 (S.D.W. Va. Aug. 6, 2014); *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3882186, at *4 (S.D.W. Va. Aug. 7, 2014) (same); *see also* Ex. N, *Carlino v.*

Ethicon, Inc., June Term, No. 3470 (Phila. Cnty. Ct. Com. Pl. Jan. 19, 2016) (excluding the "Top Ten" presentation).

The same ruling is warranted here. Mr. Luscombe, who prepared the PowerPoint, testified that it was shared at a training event for sales representatives and was "designed as a joke as something to lighten up the event." *See* Ex. O, Luscombe 7/30/13 Dep. Tr. 577:22-578:3. Luscombe explained that it was intended to mimic David Letterman's "Top Ten list," and that the listed items are "absolutely absurd and . . . have no basis for reality but they are humorous to the audience." *Id.* at 578:17-579:3. Among other things, it joked about the profit motive for selling TVT-O. Another Ethicon witness stressed that the list reflects Brian Luscombe saying that, and not Ethicon. Ex. P, Smith 5/16/13 Dep. Tr. 364:3-368:11.

For all these reasons, Mr. Luscombe's "Top Ten" list should be excluded here just as it was in *Huskey*, *Edwards*, and *Carlino*.

Motion in Limine No. 12: The Court should exclude evidence of any alleged complications associated with the device other than those alleged by Ms. Herrera-Nevarez.

Plaintiff's exhibit and deposition designations are flooded with complications Ms. Herrera-Nevarez has not experienced, such as groin pain, thigh pain, leg pain, mesh erosion, and mesh exposure. Evidence and testimony about these complications should be excluded because they are irrelevant, would be confusing to the jury, and unduly prejudicial to Ethicon. Plaintiff's expert, Dr. Rosenzweig, admitted that no medical doctor (including himself) has ever made a clinical finding of TVT-O mesh erosion in this case. Ex. Q, Rosenzweig 3/12/16 Dep. Tr. 104:20-24, 105:6-8, 105:10-17. In fact, Dr. Rosenzweig's case specific expert report does not even reference any claim regarding groin pain, leg pain, thigh pain, mesh erosion or mesh exposure. Ex. R, Rosenzweig Report at 24. Likewise, there is no evidence in this case that Ms. Herrera-Nevarez has ever experienced leg or groin pain because of her TVT-O. *See* Ex. S,

Vassallo 12/16/15 Dep. Tr. 195:19-24 (confirming that Ms. Herrera-Nevarez never reported leg pain or groin pain to him).

As the MDL court has determined on multiple occasions, "[e]vidence of complications that a plaintiff did not experience is irrelevant and lacking in probative value." *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4500767, at *5 (S.D.W. Va. Aug. 26, 2016). This Court should reach the same conclusion.

Motion in Limine No. 15: The Court should exclude certain emails as irrelevant, prejudicial, and hearsay.

Ethicon anticipates that Plaintiff will attempt to introduce at trial the following emails:

1. Ex. T, a February 27, 2004 email chain between Dan Smith and Janice Burns where, in response to a physician's report that he noticed "that small blue particles kept falling off the mesh," Dan Smith made the comment that sales representatives and surgeons should be told "UPFRONT that they will see BLUE sh*t and it is OK." (emphasis in original);
2. Ex. U, an October 15, 2002, internal email string between Axel Arnaud and Martin Weisberg in which Dr. Arnaud reviewed Dr. Weisberg's draft report on PROLENE* soft mesh and expressed his concern about a statement contained in that report about potential complications, "Fistula [and] Erosions," noting that "[t]his is a problem which arises rather commonly in practice even with polypropylene and it might be wise to be more elusive on this."

The emails should be excluded because they are irrelevant and their admission would result in unfair prejudice, juror confusion, and undue delay. FED. R. EVID. 401, 402, and 403.

The emails are also hearsay and do not fit within any apparent exception to the hearsay rule. They are not business records under Federal Rule of Evidence 803(6) because it was not a business duty of the declarant to record these emails. Thus, they were not prepared in the "regular course of business" or in the "regular practice of that business" as Rule 803(6) requires.

Nor do the emails constitute "notice." They do not involve Ms. Herrera-Nevarez or TVT-O. In light of these differences and the circumstances of the emails, the probative value of the emails—if any—is very little and is outweighed by the risk of unfair prejudice and juror

confusion stemming from the inflammatory language in the emails. *See* FED. R. EVID. 403. In particular, the Court should preclude Plaintiff's counsel from referring at trial to "blue sh*t" since this reference has no relation to the facts at issue in Plaintiff's case, and would merely inflame the jury and unfairly prejudice Ethicon. The emails should therefore be excluded.

Motion in Limine No. 17: Plaintiff should not be permitted to present photographic or video depictions of any mesh surgical procedures.

Ethicon anticipates that Plaintiff may attempt to introduce photographic or video depictions of pelvic organ prolapse or stress urinary incontinence surgical procedures. *See, e.g.*, Ex. P115 (Video – TVT-O Procedures for SUI). Ethicon moves to exclude all mesh surgical procedure videos and any other videos or photographs of actual surgery on the grounds that (1) they are irrelevant, and (2) even if they had some probative value, it would be outweighed by their unfair prejudicial effect. *See* FED. R. CIV. P. 401, 402 and 403. The mesh videos (which are bloody and graphic, not intended for lay audiences, and have caused at least one juror to have to leave the courtroom) are not relevant to any genuine issue in the case and, to the extent they may be considered relevant, their purpose can be more fairly satisfied by using animations.

Other courts in the mesh litigation have granted this motion and excluded this evidence. *See* Ex. V, Order, *Carlino v. Ethicon*, June Term 2013, No. 3470 (Phila. Cnty. Ct. Com. Pl. Jan. 19, 2016); Ex. W, Trial Tr. at 13:23-14:6, *Engleman v. Ethicon, Inc.*, Mar. Term 2014, No. 5384 (Phila. Cnty. Ct. Com. Pl. Apr. 12, 2017); Ex. X, Order, *Beltz v. Ethicon, Inc.*, June Term 2013, No. 3835 (Phila. Cnty. Ct. Com. Pl. May 3, 2017). This Court should reach the same conclusion.

Motion in Limine No. 18: Plaintiff should not be permitted to present evidence or argument regarding mesh devices not implanted in Ms. Herrera-Nevarez.

Ethicon anticipates that Plaintiff will attempt to introduce evidence concerning mesh devices not implanted in Ms. Herrera-Nevarez. The Court should exclude this evidence because it is irrelevant and unfairly prejudicial, especially because evidence of devices designed to treat

pelvic organ prolapse concern a medical condition that Ms. Herrera-Nevarez did not have and for which she was not treated with any device. These products have different shapes and methods of insertion from devices used to treat stress urinary incontinence, have no bearing on the issues in this case, have very different regulatory histories, and are no longer on the market—facts that would invite jury confusion, unfair prejudice, and result in waste of time in this nine-day trial.

Similarly, evidence of other devices to treat stress urinary incontinence, such as TVT-Secur and TVT-Abbrevo, are not relevant to Plaintiff's claims. Specifically, evidence pertaining to TVT-Secur (launched in 2006; decommercialized in 2012) and TVT-Abbrevo (launched in 2010) should be excluded because these devices were not available at the time of Ms. Herrera-Nevarez's May 2005 procedure. In addition, unlike TVT-O, TVT-Secur is no longer sold, which again would create juror confusion, result in a waste of time, and lead to unfair prejudice.

Accordingly, the Court should exclude evidence of other devices under Rules 401, 402, and 403 as courts have done in other mesh trials.[9]

Motion in Limine No. 19: Plaintiff should not be permitted to present evidence or argument regarding post-sale company documents authored by Dr. Meng Chen.

Based on Plaintiff's deposition designations, Plaintiff intends to introduce into evidence exhibits T-3321, T-3322, T-3324, T-3325, and T-3326, collectively attached as Ex. CC, which were authored by Dr. Meng Chen of Ethicon ***after Plaintiff's May 2005 procedure***. These

[9] *See, e.g.*, Ex. Y, Dep. Designation Hr'g Tr. at 101:11-21, 115:9-22, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473 (S.D.W. Va. Nov. 24, 2014) (excluding evidence pertaining to hernia mesh in case involving pelvic organ prolapse on the grounds that it is "a different product" and wasn't ever available to the implanting physician); Ex. Z, Pre-Trial Mots. Hr'g Tr. at 69:21-70:3, *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972 (S.D.W. Va. Aug. 15, 2014) (excluding evidence pertaining to product used to treat pelvic organ prolapse in case involving stress urinary incontinence because evidence would be "extremely confusing and misleading and prejudicial"); Ex. AA, Pre-Trial Mots. Hr'g Tr. at 25:11-17, 29:10-19, *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201 (S.D.W. Va. Aug. 14, 2014) (same); Ex. BB, Trial Tr. at 1212:14-1222:24, *Budke v. Ethicon, Inc.*, No. 10CM-CC00085 (Mo. Cir. Ct. Camden Cnty. Jan. 9, 2015) (excluding evidence of different product in case involving pelvic organ prolapse).

documents concern Dr. Chen's investigation into whether to update the TVT-O Instructions For Use ("IFU") with information regarding the risk of chronic dyspareunia.

Illinois courts apply the learned intermediary doctrine to claims arising from the use of prescription medical devices. *Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 42 (Ill. 2002). Under that doctrine, Ethicon had a duty to warn only the prescribing physician, Dr. Vassallo in this case. *See id.*

The issue of whether Ethicon adequately warned Dr. Vassallo of dyspareunia *before* Ms. Herrera-Nevarez's May 2005 mesh implant procedure is not informed by company documents that were authored *after* her procedure. Accordingly, these documents are not relevant to Plaintiff's failure to warn claim.

The lack of probative value of these exhibits is even further illustrated by consideration of Dr. Vassallo's testimony. Specifically, he knew about the risk of dyspareunia before Ms. Herrera-Nevarez's implant procedure. Ex. DD, Vassallo 12/16/15 Dep. Tr. 111:11-114:16. Further, he did not rely on the TVT-O Instructions for Use (IFU) in his recommendation of the device to Ms. Herrera-Nevarez, for knowledge of risks related to the device, or for information on how to implant the device. *See id.* at 156:24-157:18. In fact, he testified that he has not looked at an IFU "for years" because he implants "hundreds of slings every year." *See id.* at 41:15-42:8, 43:20-44:1. As there is no duty to warn of a risk already known, and additionally Dr. Vassallo did not rely on the TVT-O IFU in his prescribing decision here, these documents relating to consideration of post-implant changes to the IFU are not relevant and present a significant risk of jury confusion. *See Proctor v. Davis*, 682 N.E.2d 1203, 1211 (Ill. App. Ct. 1997) ("In Illinois, there is no duty to warn of a risk that is already known by those to be

warned.") (citing *Kokoyachuk v. Aeroquip Corp.*, 526 N.E.2d 607 (Ill. App. Ct. 1988)); *see also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 741 (S.D.W. Va. 2014).

For these reasons, the Meng Chen documents should be excluded.

Motion in Limine No. 20: Plaintiff should not be permitted to present evidence or argument regarding the Johnson & Johnson Credo.

Johnson & Johnson has a company Credo that discusses a "first responsibility" to patients, says everything the company does must be of "high quality," talks about responsibility to the community, and says mistakes should be paid for. *See* Ex. EE, Johnson & Johnson Credo. Ethicon anticipates that Plaintiff may make certain inappropriate arguments at trial, including arguing that Ethicon has allegedly not followed the Credo. The Credo is not required by law and is not the standard by which Ethicon's conduct should be judged. Thus, the Credo should be excluded under Rules 401, 402, and 403 to avoid an implication that it sets forth a legal standard. *See In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2016 WL 4493685, at *3 (S.D.W. Va. Aug. 25, 2016) (excluding expert testimony on Credo because "[l]iability is not predicated on a company's compliance with its own credos or codes; liability is instead predicated on the legal standards of the case"); *In re Tylenol (Acetaminophen) Marketing, Sales Practices and Products Liab. Litig.*, No. 2436, 2016 WL 807377, at *8 n.22 (E.D. Pa. March 2, 2016) (excluding the Credo because it expresses a standard of conduct higher than the legal standard, and so would be confusing to a jury).

CERTIFICATION OF COMPLIANCE WITH LOCAL RULE 37.2

On July 17, 2017 at 2:00 p.m., Tarek Ismail and Laura Sexton, counsel for Ethicon, met and conferred in person with counsel for Plaintiff, Jeffrey Kuntz, Steve Phillips, and Elise Waisbren, at 161 N. Clark Street, Chicago, IL 60601. The parties discussed all of the above motions in limine, and made a good faith effort to resolve the issues in dispute. Although the

parties reached agreement on a substantial number of issues, they were unable to reach an agreement on the above motions, and have determined that the subject matter of such motions is actually in dispute.

Dated: July 19, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on July 19, 2017, a copy of the foregoing was filed electronically via the Court's CM/ECF system, which will have sent notice to the attorneys of record in this matter.

/s/ *Sherry A. Knutson*
Sherry A. Knutson

One of the Attorneys for Defendants Ethicon, Inc. and Johnson & Johnson